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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,538	03/11/2005	Chester Sutterlin	072US1	8929
Nuvasive Portfolio IP P O Box 52050 Minneapolis, MN 55402			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 02/26/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,538

Applicant(s)

SUTTERLIN ET AL.

Examiner

JERRY CUMBERLEDGE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 58-65 and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Pat. 5,733,288) in view of Ouchi (US Pat. 5,899,850).

Allen discloses a method for removing intervertebral disc material, comprising the steps of: creating a working channel from a patient's skin to an intervertebral disc space [since the device can be used on bone, column 1, lines 55-63, and specifically within the spine in order to correct spinal problems, column 1, lines 10-15, in order to remove fibrous soft tissue (*e.g.* a spinal disc) and since to remove this tissue the device must necessarily first reach the tissue (*e.g.* the spinal disc) through a channel, which would lead to the intervertebral disc space, where the disc being removed resides], inserting a brush member into said intervertebral disc space (since to remove the fibrous tissue, *e.g.* the spinal disc, the brush member must be placed within the disc space, where the disc resides), said brush member having a plurality of bristle members (Fig. 2, near ref. 10) defining a capacity for carrying intervertebral disc material (Fig. 10, since disc material can be received within the spaces between the bristles)(column 3, lines 16-19); manipulating said brush member within said intervertebral disc space to receive intervertebral disc material within said brush member (column 5, lines 1-4); and

removing said brush member from said intervertebral disc space (Fig. 2, since the device is clearly designed to be removed from the body when the surgery is completed). The step of creating a working channel to the intervertebral disc space is accomplished via at least one of percutaneous surgical procedure and an open surgical procedure (since the device, at the very least, in order to reach the bone and soft tissue, column 3, lines 15-19, the device must pass through the skin). The brush member includes a stem member (Fig. 2, ref. 20), and further includes the step of providing a drive assembly (column 5, lines 1-6, i.e. the rotary hand piece) capable of engaging with said stem member for manipulating said brush member within said intervertebral disc space (column 5, lines 1-6). The drive assembly comprises one of a powered drive assembly coupled to said stem member and a manual drive assembly coupled to said stem member (column 5, lines 1-6, i.e. the rotary hand piece). The powered drive assembly is a power drill (column 2, lines 59-62). The manual drive assembly includes a handle member capable of being coupled to said stem member (Figs. 5-7, column 5, lines 1-6, i.e. the rotary hand piece must comprise a stationary portion to grip, or the device would spin from the surgeons hands when used). The drive assembly includes a stop member (Fig. 5, lip to the right of the brush member) coupled to said stem member for controlling the depth to which said brush member can be advanced into said intervertebral disc space.

Allen discloses the claimed invention except for the length of the brush member ranging from 0.25-4.0 inches, the diameter of the brush member ranging from 0.082 to

1.225 inches and the bristle members disposed in a helical configuration. Allen discloses that the bristles are used to remove tissue (abstract).

Ouchi discloses a device (Fig. 1) with a brush (Fig. 1, ref. 2) that comprises bristles that are arranged in a helical pattern (Fig. 1, ref. 2A). The bristles are used for removing tissue (column 5, lines 50-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the bristles of Allen with helical bristles as taught by Ouchi, in order to achieve the predictable result of removing tissue.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the brush member with a length ranging from 0.25 to 4.0 inches and a diameter ranging from 0.082 to 1.225 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, Allen discloses the general condition that the brush can be used in methods involving spinal diseases (column 1, lines 10-26), which would require smaller brush sizes.

With regard to claims 60, 61, 68 and 69, Allen discloses the claimed method except for the step of inserting a brush member includes, prior to said step of inserting said brush member, positioning a protector near an entrance into said intervertebral disc space for establishing a barrier between said brush member and at least one of neural tissue, dura tissue, and vasculature adjacent to said entrance. The protector comprises

a cannula dimensioned to extend to said entrance of said intervertebral disc space, said cannula having an inner lumen dimensioned to slideably receive said brush member for passage into said intervertebral disc space. The cannula includes a lip member at a distal end thereof dimensioned to retract at least one of said neural tissue, dura tissue, and vasculature adjacent to said spine. The inner lumen of said cannula and said brush member have approximately the same cross-sectional shape.

Ouchi discloses a method of inserting a brush member (Fig. 16, ref. 2) into tissue (column 1, lines 5-10), wherein prior to said step of inserting said brush member, positioning a protector (Fig. 16, ref. 6) which establishes a barrier between said brush member and other tissue, since the protector surrounds the brush (Fig. 16). The protector comprises a cannula (Fig. 16, ref. 6) dimensioned to extend to said entrance of said intervertebral disc space, said cannula having an inner lumen (Fig. 16, near ref. 14A) dimensioned to slideably receive said brush member for passage into said intervertebral disc space (Fig. 16 and Figs. 1, 2A, 2B). The cannula includes a lip member (Fig. 4, e.g. ref. 5) at a distal end thereof dimensioned to retract at least one of said neural tissue, dura tissue, and vasculature adjacent to said spine (Fig. 4), since as it expands it can retract tissue. The inner lumen of said cannula and said brush member have approximately the same cross-sectional shape (Fig. 16). This tube is useful in allowing the brush to be used for cytology purposes and prevents the cells collected from being knocked off of the brush (column 1, lines 10-30).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Allen with the steps of using a

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protector as taught by Ouchi in order to allow the brush of Allen to be used for cytology and puposes and prevent the cells collected from being knocked off of the brush (column 1, lines 10-30).

Claims 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Pat. 5,733,288) in view of Ouchi (US Pat. 5,899,850) in view of Ouchi (US Pat. 6,210,377 B1).

Allen in view of Ouchi (US Pat. 5,899,850) disclose the claimed invention except for the protector comprising a retractor having at least one blade member for establishing a barrier between said brush member and said body tissue adjacent to said entrance. The body tissue adjacent to said entrance includes at least one of neural tissue and dura tissue of the spine, and wherein said retractor includes a first blade member for retracting said neural tissue and a second blade member for retracting said dura tissue. The first blade member and second blade member have a fixed angle therebetween. The first blade member and second blade member have a variable angle therebetween. The retractor includes a handle assembly for varying said angle between said first blade member and said second blade member.

Ouchi (US Pat. 6,210,377 B1) discloses placing a blade on the end of a retractor (column 21, lines 13-16), in order to assist in proper insertion of other devices through the retractor (column 21, lines 7-12).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the retractor of Ouchi (US Pat. 5,899,850)

with the blade of Ouchi (US Pat. 6,210,377 B1), in order to assist in proper insertion of other devices through the retractor (column 21, lines 7-12). By constructing the device in this manner, the retractor of Ouchi (US Pat. 5,899,850) would then be provided with two bladed members (e.g. a first blade member and a second blade member), since the end of the retractor of Ouchi (US Pat. 5,899,850) is split in two different sections (Fig. 2B, ref. 14A). The two sections would be capable of remaining stationary to each other, or moving relative to each other (column 8, lines 47-54).

Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Pat. 5,733,288) in view of Ouchi (US Pat. 5,899,850) in view of Worthen et al. (US Pat. 5,445,164).

Allen in view of Ouchi discloses the claimed invention except for the manual drive assembly including an extension member coupled to said handle and a quick-connect coupling assembly for releasable connection to said stem member.

Worthen et al. discloses a quick-connect assembly coupled to a handle (column 1, lines 37-39), which is used to quickly detach components from each other (column 1, lines 37-39).

It would have been obvious to have constructed the device of Allen in view of Ouchi with a quick-connect assembly as taught by Worthen et al., in order to allow one to quickly detach the components from each other (column 1, lines 37-39).

Response to Arguments

Applicant's arguments with respect to claims 58-74 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

